IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY
London Division

THE UNITED STATES OF AMERICA *ex rel.* (UNDER SEAL),	:	
Plaintiffs,	:	
	:	Civil Action No.
v.	:	
	:	6:11-cv-00081-GFVT
(UNDER SEAL)	:	
Defendants.	:	

FIRST AMENDED COMPLAINT FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY
London Division

THE UNITED STATES OF AMERICA *ex rel.* MICHAEL R. JONES, M.D. 1720 Nicholasville Road, Suite 601 Lexington, Kentucky 40502 and THE UNITED STATES OF AMERICA *ex rel.* PAULA W. HOLLINGSWORTH, M.D. 1720 Nicholasville Road, Suite 601 Lexington, Kentucky 40502 and THE UNITED STATES OF AMERICA *ex rel.* MICHAEL G. RUKAVINA, M.D. 1720 Nicholasville Road, Suite 601 Lexington, Kentucky 40502 **Plaintiffs,** v. SAINT JOSEPH HEALTH SYSTEM, INC. 200 Abraham Flexner Way Louisville, Kentucky 40202 **SERVE ON REGISTERED AGENT:** CT Corporation System 306 West Main Street Suite 512 Frankfort, Kentucky 40601 and SJL PHYSICIAN MANAGEMENT SERVICES, INC. 200 Abraham Flexner Way Louisville, Kentucky 40202	**Civil Action No.** 6:11-cv-00081-GFVT **COMPLAINT FILED IN CAMERA AND UNDER SEAL** **31 U.S.C. § 3730(b)(2)** **DO NOT ENTER IN ECF/PACER** **DO NOT PUT IN PRESS BOX**

SERVE ON REGISTERED AGENT:
CT Corporation System
306 West Main Street , Suite 512
Frankfort, Kentucky 40601

and

MEDICAL SPECIALISTS OF
KENTUCKY, P.S.C.
1210 West 5th Street
London, Kentucky, 40741

SERVE ON REGISTERED AGENT:
Satyabrata Chatterjee, M.D.
1210 West 5th Street
London, Kentucky 40741

and

CUMBERLAND CLINIC, P.L.L.C.
107 Roy Kidd Avenue
Corbin, Kentucky 40701

SERVE ON REGISTERED AGENT:
Satyabrata Chatterjee, M.D.
1210 West 5th Street
London, Kentucky 40741

and

HEART CLINIC OF SOUTHEAST
KENTUCKY, P.S.C.
1380 Highway 192 East
London, Kentucky 40741

SERVE ON REGISTERED AGENT:
Ashwini Anand
1380 Highway 192 East
London, Kentucky 40741

and

MANAGEMENT SERVICE ORGANIZATION
OF KENTUCKY, INC.
1210 West 5th Street, Suite 201
London, Kentucky 40741

SERVE ON REGISTERED AGENT:
Sumita Chatterjee
1210 West 5th Street, Suite 201
London, Kentucky 40741

and

SATYABRATA CHATTERJEE, M.D.
1707 Cumberland Falls Highway
Corbin, Kentucky 40701

and

ASHWINI ANAND, M.D.
740 Philpot Road
London, Kentucky 40744

and

SANDESH PATIL, M.D.
285 Beechwood Drive
London, Kentucky 40744,

Defendants.

FIRST AMENDED COMPLAINT

COMES NOW, through the undersigned counsel, Relators Michael R. Jones, M.D., Paula Hollingsworth, M.D., and Michael Rukavina, M.D., on behalf of themselves and the United States of America ("United States"), and bring this *qui tam* action under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA"), the Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b ("Anti-Kickback Statute"), and the Ethics in Patient Referrals Act of 1989, 42 U.S.C. § 1395nn ("Stark Law") to recover monetary damages, civil penalties, and all other remedies for violations of the Federal healthcare programs, including Medicare, Medicaid, the Civilian Health and Medical

Program of the Uniformed Services ("CHAMPUS/TRICARE"), the Veterans Administration, and the Federal Employee Health Benefits Program (collectively, "Federal Payer Programs"), and hereby allege as follows:

I. NATURE OF THE ACTION.

1. This is a *qui tam* action under federal false claims, anti-kickback, and Stark laws. The FCA was enacted in 1863 in response to "widespread corruption and fraud in the sales of supplies and provisions to the union government during the Civil War." 132 CONG. REC. H9382-03 (daily ed. Oct. 7, 1986) (statement of Rep. Glickman). The law allows a private person with knowledge of a fraud to bring an action in federal district court for himself and for the United States and States and to share in any recovery. The party is known as a Relator, and the action that a Relator brings is called a *qui tam.*

2. In this *qui tam,* Relators allege that Defendants knowingly presented and induced false and fraudulent claims and statements that were material to the government's decision to reimburse payment of claims for diagnostic and therapeutic cardiac and peripheral catheterizations, stents, pacemakers, and coronary artery bypass grafts ("CABG"), as well as associated diagnostic tests, which were not reasonable or necessary for the diagnosis or treatment of patients. Defendants' scheme knowingly caused false and fraudulent statements, certifications, and claims for payment to be submitted to the United States under the Federal Payer Programs for procedures that were not eligible for coverage and reimbursement.

3. The fraudulent course of conduct alleged in this Complaint centers on an illegal scheme to maximize the reimbursements for diagnostic and therapeutic cardiac

and vascular procedures by billing and receiving payments from the Federal Payer Programs for procedures performed on patients that were not reasonable or necessary. This Complaint challenges three types of medical procedures performed by Defendants: (i) diagnostic and therapeutic cardiac procedures for patients with coronary artery disease, including diagnostic cardiac tests, diagnostic cardiac catheterizations, cardiac angioplasties, coronary stents, and CABGs; (ii) diagnostic and surgical procedures used to implant temporary and permanent pacemaker devices in patients with heart arrhythmias; and (iii) therapeutic vascular procedures, including percutaneous transluminal arterial angioplasty and stenting in the vascular beds of patients, including the renal, iliac, and superficial femoral arteries.

4. Defendants' fraudulent course of conduct is as follows: Defendants Satyabrata Chatterjee, M.D. and Ashwini Anand, M.D., together, substantially control the cardiology and vascular practice of medicine in and around London, Kentucky. They own and operate Medical Specialists of Kentucky, P.S.C., Cumberland Clinic, P.L.L.C., and Heart Clinic of Southeast Kentucky, P.S.C. (collectively, "Defendant Clinics"). Defendant Clinics, directly and through their employees, agents, and co-conspirators, perform diagnostic testing and imaging at their offices. In circumstances where the medical tests do not warrant therapeutic procedures, or when sufficient testing has not been performed, they nonetheless refer the patients to Defendant St. Joseph Health System, Inc.'s ("St. Joseph Health System") hospitals located throughout the State of Kentucky for interventional therapeutic procedures, including angioplasties, stenting, CABGs, and pacemaker implantations. Defendants Chatterjee and Anand, directly and through Defendant Clinics, their employees, agents, and co-conspirators, knowingly have

performed a substantial number of cardiac and vascular procedures on program beneficiaries that were not reasonable or necessary for the diagnosis or treatment of the patients, as alleged herein. Defendants, directly and through Defendant Management Service Organization of Kentucky, Inc., a medical billing company owned and/or controlled by Defendant Chatterjee, have knowingly submitted, or have caused to be submitted, claims for reimbursement of such procedures to the Federal Payer Programs.

5. Upon information and belief, Defendant St. Joseph Health System, directly and through its hospitals located throughout the State of Kentucky, provides illegal kickbacks to Defendant Clinics and/or Defendants Chatterjee and Anand disguised as provider services agreements. Defendant St. Joseph Health System entered into provider services agreements with Defendant Clinics and/or Defendants Chatterjee and Anand that provide payments to induce the referral of patients exclusively to Defendant St. Joseph Health System for the cardiac and vascular procedure challenged herein. Under these agreements, Defendant Clinics and/or Defendants Chatterjee and Anand receive illegal remuneration directly or indirectly tied to each patient referred to Defendant St. Joseph Health System for the diagnostic and therapeutic cardiac and vascular tests and procedures challenged herein. Such payments are above fair market value, for services not rendered, and not commercially reasonable.

6. As part of the illegal actions in violation of healthcare laws, Defendants Chatterjee and Anand, directly and through Defendant Clinics, market their services under Defendant Premier Heart and Vascular Center, an entity that was created, owned, and operated by Defendant St. Joseph Health System. Defendant St. Joseph Health System authorized Defendant Clinics and Defendants Chatterjee and Anand to bill for

diagnostic testing and imaging performed at Defendant Clinics under the billing codes registered to Defendant St. Joseph Health System and/or Premier Heart and Vascular Center in order to capture both the physician reimbursement and the facility reimbursement (DRG and/or APC), which they were not entitled to receive.

7. As set forth below, Defendants conduct has knowingly subjected patients to unnecessarily increased risk of mortality and morbidity. As documented in the patient exemplars presented herein, patients in fact have been seriously injured.

II. JURISDICTION.

8. This Court possesses subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. §§ 3730 and 3732 because Relators seek remedies on behalf of the United States for Defendants' violations of 31 U.S.C. § 3729 which occurred in the Eastern District of Kentucky.

9. The original complaint was filed timely within the period prescribed by 31 U.S.C. § 3731(b). There was no public disclosure of the allegations or transactions set forth in this action prior to filing under 31 U.S.C. § 3730(e).

10. This Court has personal jurisdiction over the Defendants and venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c) because at least one of the Defendants can be found in, resides, transacts or has transacted, or is qualified to do business in this District. In addition, during the period challenged by this action each Defendant regularly conducted business in this judicial district, including the performance of medically unnecessary therapeutic cardiac and vascular procedures in patients.

III. PARTIES.

A. Plaintiff.

11. Plaintiff United States of America brings this action by and through its administrative agency, the United States Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS"), which is responsible for the administration of all Federal health care programs. At all times relevant to this Complaint, the United States funded the provision of medical care for eligible patients of Defendants pursuant to the Medicare program administered by CMS.

B. Relators.

12. Relator Michael R. Jones, M.D. is an individual citizen of the United States and a resident of the State of Kentucky. Dr. Jones graduated from the University of Texas Medical School with honors in 1973. Dr. Jones is board certified in internal medicine, cardiovascular diseases, and interventional cardiology. He currently practices medicine at Lexington Cardiology at Central Baptist Hospital, which specializes in interventional cardiology. In addition to his active cardiology practice, Dr. Jones has conducted numerous clinical studies and published studies in the areas of interventional cardiology, including catheterizations, and stenting. By virtue of his practice, Dr. Jones became aware of Defendants' pervasive practice of performing medically unnecessary therapeutic cardiac and vascular procedures in patients alleged herein.

13. Relator Paula W. Hollingsworth, M.D. is an individual citizen of the United States and a resident of the State of Kentucky. Dr. Hollingsworth graduated from the University of Kentucky College of Medicine in 1991, and she currently practices medicine at Lexington Cardiology at Central Baptist Hospital. Her practice specializes in

interventional cardiology, and she is board certified in cardiovascular disease and interventional cardiology. By virtue of her practice, Dr. Hollingsworth has become aware of Defendants' pervasive practice of performing medically unnecessary therapeutic cardiac and vascular procedures in patients as alleged herein.

14. Relator Michael G. Rukavina, M.D. is an individual citizen of the United States and a resident of the State of Kentucky. Dr. Rukavina graduated from Louisiana State University School of Medicine in 1987, and he currently practices medicine at Lexington Cardiology at Central Baptist Hospital. His practice specializes in interventional cardiology, and he is board certified in cardiovascular disease. By virtue of his practice, Dr. Rukavina has become aware of Defendants' pervasive practice of performing medically unnecessary therapeutic cardiac and vascular procedures in patients as alleged herein.

15. Pursuant to 31 U.S.C. § 3730(e)(4)(B), Relators are the "original source" of the information provided to the United States regarding Defendants' illegal conduct in violation of Federal laws. Relators have direct and independent knowledge of the allegations set forth herein. They notified representatives from State regulatory authorities of the wrongful actions alleged herein on November 5, 2010. In addition, they provided a copy of this Complaint and a written disclosure of substantially all material evidence prior to filing. The information concerning Defendants' misconduct was not disclosed publicly prior to Relators' original disclosure to the United States.

C. Defendants.

16. Defendant St. Joseph Health System, Inc. ("St. Joseph Health System") operates eight hospitals in central and eastern Kentucky with approximately 912 licensed

beds, 6,105 employees, and 1,300 physicians on staff. Defendant St. Joseph Health System does business as St. Joseph Hospital, St. Joseph London, St. Joseph East, The Women's Hospital at St. Joseph East, St. Joseph Berea, St. Joseph Martin, St. Joseph Jessamine, St. Joseph Mount Sterling, and Flaget Memorial Hospital. Defendant St. Joseph Health System is owned and operated by Catholic Health Initiatives ("CHI"), a national non-profit healthcare system. CHI's hospitals have a history of Anti-Kickback Statute and Stark Law violations, as well as performing medically unnecessary cardiac procedures in patients. In 2010, another CHI hospital, St. Joseph Medical Center in Towson, Maryland, entered into a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services for violations of the Anti-Kickback Statute and Stark Law, as well as billing the Federal Payer programs for medically unnecessary stents. Defendant St. Joseph Health System is organized and existing under the laws of Kentucky with its principal place of business located at 200 Abraham Flexner Way, Louisville, Kentucky 40202. As set forth herein, Defendant St. Joseph Health System, directly and through its hospitals, agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at its facilities and presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant St. Joseph Health System may be served through its registered agent, CT Corporation System, at 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

17. Defendant SJL Physician Management Services, Inc. operates under the name Premier Heart and Vascular Center (collectively "Premier Heart and Vascular Center").[1] It was created, owned, and operated by Defendant St. Joseph Health System. It is organized and existing under the laws of Kentucky with its principal place of business located at 200 Abraham Flexner Way, Louisville, Kentucky 40202. It also has a facility located at 1210 West 5th Street, London, Kentucky 40741. Upon information and belief, Premier Heart and Vascular Center does not satisfy the requirements for provider based entity status or free standing facility status as set forth in 42 C.F.R. § 413.65 *et seq.* As set forth herein, Defendant Premier Heart and Vascular Center, directly and through its agents, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at its facilities and presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Premier Heart and Vascular Center may be served through its registered agent, CT Corporation, at 306 West Main Street, Suite 512, Frankfort, Kentucky 40601.

18. Defendant Medical Specialists of Kentucky, P.S.C. ("Medical Specialists of Kentucky") is a cardiology clinic owned and operated by Defendant Satyabrata Chatterjee, M.D. It is organized and existing under the laws of Kentucky with its principal place of business located at 1210 West 5th Street, London, Kentucky 40741. Upon information and belief, Defendant Medical Specialists of Kentucky does not satisfy the requirements for provider based entity status or free standing facility status as set

[1] On May 26, 2010, Defendant St. Joseph Health System filed a Certificate of Assumed Name for "Premier Heart and Vascular Center" with the Kentucky Secretary of State.

forth in 42 C.F.R. § 413.65 *et seq.* As set forth herein, Defendant Medical Specialists of Kentucky, directly and through its agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System and presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Medical Specialists of Kentucky may be served through its registered agent, Satyabrata Chatterjee, at 1210 West 5th Street, London, Kentucky 40741.

19. Defendant Cumberland Clinic, P.L.L.C. ("Cumberland Clinic") is a cardiology clinic owned and operated by Defendants Satyabrata Chatterjee, M.D. and Ashwini Anand, M.D. It is organized and existing under the laws of Kentucky with its principal place of business located at 107 Roy Kidd Avenue, Corbin, Kentucky 40701. Upon information and belief, Cumberland Clinic does not satisfy the requirements for provider based entity status or free standing facility status as set forth in 42 C.F.R. § 413.65 *et seq.* As set forth herein, Defendant Cumberland Clinic, directly and through its agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System and presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Cumberland Clinic may be served through its registered agent, Satyabrata Chatterjee, at 1210 West 5th Street, London, Kentucky 40741.

20. Defendant Heart Clinic of Southeast Kentucky, P.S.C. ("Heart Clinic of Southeast Kentucky") is a cardiology clinic owned and operated by Defendant Ashwini Anand, M.D. It is organized and existing under the laws of Kentucky with its principal place of business located at 1380 Highway 192 East, London, Kentucky 40741. Upon information and belief, Defendant Heart Clinic of Southeast Kentucky does not satisfy the requirements for provider based entity status or free standing facility status as set forth in 42 C.F.R. § 413.65 *et seq*. As set forth herein, Defendant Heart Clinic of Southeast Kentucky, directly and through its agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System and presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Heart Clinic of Southeast Kentucky may be served through its registered agent, Ashwini Anand, M.D., at 1380 Highway 192 East, London, Kentucky 40741.

21. Defendant Management Service Organization of Kentucky, Inc. ("MSO") is a medical billing company responsible for billing the Federal Payer Programs for medical procedures performed by Defendants Medical Specialists of Kentucky, Cumberland Clinic, Heart Clinic of Southeast Kentucky, and St. Joseph Health System. MSO previously was owned by Defendant Chatterjee, and is presently owned and operated by Sumita Chatterjee, his wife. Upon information and belief, Defendant Chatterjee continues to have an ownership and/or financial interest and exerts control over the operations of Defendant MSO. As set forth herein, Defendant MSO, directly

and through its agents, employees, affiliates, and co-conspirators, knowingly presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant MSO may be served through its registered agent, Sumita Chatterjee, at 1210 West 5th Street, Suite 201, London, Kentucky 40741.

22. Defendant Satyabrata Chatterjee, M.D. ("Defendant Chatterjee") is a staff cardiologist at St. Joseph London Hospital. He also owns and operates, in whole or in part, Defendants Medical Specialists of Kentucky and Cumberland Clinic, and he has a financial and/or ownership interest in Defendant MSO or otherwise controls its operations. As set forth herein, Defendant Chatterjee, directly and through his corporations, agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System. He presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Chatterjee may be served at 1707 Cumberland Falls Highway, Corbin, Kentucky 40701.

23. Defendant Ashwini Anand, M.D. ("Defendant Anand") is a staff cardiologist at St. Joseph London Hospital. He also owns and operates, in whole or in part, Defendants Heart Clinic of Southeast Kentucky and Cumberland Clinic. As set forth herein, Defendant Anand, directly and through his corporations, agents, employees, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic

and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System. He presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Anand may be served at 740 Philpot Road, London, Kentucky 40744.

24. Defendant Sandesh Patil, M.D. ("Defendant Patil") is a staff cardiologist at St. Joseph London Hospital. He is also a director and cardiologist at Defendant Medical Specialists of Kentucky. As set forth herein, Defendant Patil, directly and through his corporate, agents, affiliates, and co-conspirators, knowingly performed medically unnecessary diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System. He presented or caused to be presented false claims for payment to the Federal Payer Programs for the procedures alleged herein, and knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Defendant Patil may be served at 285 Beechwood Drive, London, Kentucky 40744.

25. At all times relevant to this Complaint, Defendants conspired to violate the false claims, anti-kickback, and Stark laws in connection with the performance of medically unnecessary diagnostic and therapeutic cardiac and vascular procedures in patients.

IV. THE FEDERAL PAYER PROGRAMS.

26. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, known as the Medicare program. Medicare is a health financing program that pays for the costs of certain services and care provided to eligible aged and

disabled beneficiaries. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A.

27. The Medicare Program has several parts, one of which, commonly referred to as "Medicare Part A," provides hospital insurance benefits for eligible aged and disabled beneficiaries. Medicare Part A covers certain costs of hospital and related post-hospital extended services, including home health services and hospice care, as provided in 42 U.S.C. §§ 1395c-1395i-4.

28. The Department of Health and Human Services ("HHS") is responsible for the reimbursement, administration, and supervision of the Medicare Program. The Centers for Medicare & Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration, is a component of HHS and is directly responsible for the administration of the Medicare Program. To assist in the administration of Medicare Part A, HHS contracts with entities known as "fiscal intermediaries" and "carriers." 42 U.S.C. §1395h; see 42 C.F.R. Part 421, Subparts A and B. These fiscal intermediaries and carriers review claims to determine whether they are appropriate for reimbursement under Medicare Part A (inpatient hospital and related services) and Medicare Part B (outpatient hospital and physician services). The rules governing the Medicare Program are set forth in the statute (the "Medicare Act"), regulations, and the manuals, rulings and other policy statements issued by CMS, including but not limited to the Provider Reimbursement Manual ("PRM") and the CMS Online Manual System ("MS").

29. To be eligible for reimbursement under the Medicare Program, a provider of services is required to enter into a contract, known as a provider agreement, with HHS. 42 U.S.C. § 1395cc; PRM § 2402.2; Medicare General Information, Eligibility and

Entitlement Manual (MS Pub. 100-1) Ch. 5 § 10.1. A provider is required to comply with the Medicare laws, regulations and policies governing the Medicare Program. MS Pub. 100-1 Ch. 1 § 20.3.

30. The Balanced Budget Act of 1997 established a new Part C of the Medicare program, known as the Medicare+Choice (M+C) beginning in January 1999. M+C plans typically provided health care coverage that exceeded the coverage of original fee-for-service Medicare at a lower cost to Medicare beneficiaries. As part of the M+C program, the Balanced Budget Act authorized CMS to contract with public or private organizations offering a variety of health plan options for Medicare beneficiaries, such as Health Maintenance Organizations ("HMOs") and Preferred Provider Organizations ("PPOs"). The M+C program in Part C of Medicare was replaced by the Medicare Advantage ("MA") program pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), enacted on December 8, 2003. The MA program retains many provisions in the M+C program while updating and improving choice of plans for beneficiaries and restructuring how plans are paid. Medicare Advantage is available to beneficiaries enrolled in Medicare Parts A and B.

31. Under the prospective payment system ("PPS"), hospitals are paid on the basis of prospectively determined fixed rates, which vary according to the type and category of hospital treatment received. 42 U.S.C. § 1395ww(d). The specific rate to be paid depends upon which diagnosis-related group best characterizes the patient's condition and treatment.

32. CMS utilizes the Current Procedural Terminology ("CPT") coding system, which is a common language for coding physician services and procedures for purposes of seeking reimbursement from the Medicare Program. Physicians under the Medicare system submit claims for reimbursement electronically or with the use of forms (CMS 1500), which are completed by using the appropriate CPT code to describe the services rendered and billed.

33. Medicare is permitted to pay only for expenses that are "reasonable and necessary for the diagnosis and treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A). Regulations, national coverage determinations, and local coverage determinations specify services that are covered as medically reasonable and necessary. It is illegal to code or bill for services not actually rendered, provide medically unnecessary services,[2] upcode bills,[3] unbundle charges,[4] submit duplicate billing, or otherwise fail to follow established billing and coding guidelines.

34. Hospitals and physicians enter into a Provider Agreement to establish their eligibility to seek such reimbursement from Medicare. The Provider Agreement states, in part:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the

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[2] Seeking payment for medically unnecessary services is an act designed to obtain reimbursement for a service that is not warranted by the patient's current and documented medical condition. 42 U.S.C. § 1395y(a)(1)(A) ("no payment may be made under part A or part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member.").

[3] Upcoding involves the use of a billing code that provides a higher rate of payment than a code that actually reflects the patient's condition or the service furnished to the patient.

[4] Unbundling involves the submission of bills in a fragmented manner in order to maximize the reimbursement for various tests or procedures that must be billed together at a reduced cost.

> claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

35. As a precondition to payment, Medicare requires healthcare providers to submit quarterly Credit Balance Reports, CMS Form 838, to Fiscal Intermediaries. As alleged herein, health care providers have made false statements and claims to the United States by failing to report overpayments on their Credit Balance Reports in order to avoid their obligation to repay overpayments owed to Medicare based on the payment for non-covered services in the form of medically unnecessary cardiac and vascular procedures. On the Credit Balance Reports, providers are required to disclose all credit balances defined as any "improper or excess payment made to a provider as the result of patient billing or claims processing errors" such as "payments for . . . non-covered services." Medicare regulations require providers to repay their credit balances at the same time that they report them on Form 838.

36. Additionally, as a precondition to payment, Medicare requires healthcare providers to submit annually Form 2552, more commonly known as the Hospital Cost Report. After the end of each fiscal year, the Hospital Cost Report must be filed with the Fiscal Intermediary stating the amount of reimbursement the provider believes it is due for the year. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. *See also* 42 C.F.R. § 405.1801(b)(1). Medicare relies upon the Hospital Cost Report to determine whether the provider is entitled to more reimbursement than already received through interim payments, or whether the provider has been overpaid and must reimburse Medicare. 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1). Medicare payments for inpatient hospital services are determined by the claims submitted by the provider for particular patient

discharges during the course of the fiscal year. On the Hospital Cost Report, the Medicare liability for inpatient services is then totaled with any other Medicare liabilities to the provider. This total determines Medicare's true liability for services rendered to Medicare beneficiaries during the course of a fiscal year. From this sum, the payments made to the provider during the year are subtracted to determine the amount due the Medicare program or the amount due the provider.

37. Every Hospital Cost Report contains a "certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator stating that the Hospital Cost Report is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions. The instructions to the certification state that the services described in the Cost Report must comply with all Medicare program requirements. The Hospital Cost Report includes the following statement:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result.

In addition, the person certifying the report is required to sign a statement that:

> To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

38. Each service or procedure involving the performance of interventional therapeutic cardiac and vascular procedures carried with it a certification by the

healthcare provider that the service complied with the program requirements and was medically reasonable and necessary. These certifications were expressly or by implication false because Defendants knew that such procedures were not reasonable or medically necessary and that billing the Federal Payer Programs for the performance of such procedures violated federal and state anti-kickback laws.

39. The unnecessary procedures resulted in overpayments by the Federal Payer Programs. Defendants were required to disclose the overpayments in Credit Balance Reports and Hospital Cost Reports, but failed to do so.

B. The Medicaid Program.

40. Title XIX of the Social Security Act ("Medicaid" or the "Medicaid Program") authorizes grants to States for medical assistance to children and blind, aged and disabled individuals whose income and resources are not sufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396; 42 C.F.R. § 430.0; see 42 U.S.C. §§ 1396-1396v. The Medicaid Program is jointly funded by the Federal Government and participating States. The amount of Federal funding in a State's program (Federal Financial Participation) is determined by a statutory formula set forth in 42 U.S.C. §§ 1396b(a) and 1396d(b).

41. A State that elects to participate in the Medicaid Program must establish a plan for providing medical assistance to qualified beneficiaries. 42 U.S.C. § 1396a(a)-(b); see 42 C.F.R. Part 430, Subparts A and B; CMS State Medicaid Manual § 13025. In exchange, the Federal Government, through CMS, pays to the State the federal portion of the expenditures made by the State to providers, and ensures that the State complies with

minimum standards in the administration of the Medicaid Program. 42 U.S.C. §§ 1396, 1396a, and 1396b.

42. The State of Kentucky has elected to participate in the Medicaid Program, has established a State plan under the Medicaid Program, and has promulgated regulations that implement the State plan. *See* K.R.S. § 205.510 *et seq.* The Kentucky Cabinet for Health and Family Services, Department of Medicaid Services is the sole Medicaid agency that has contracted with HHS to administer or supervise the Medicaid Program in the State of Kentucky. K.R.S. § 205.510 *et seq.* *See* 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10(b).

43. Individuals or entities that provide services to Medicaid beneficiaries in Kentucky submit claims for payment to the Medicaid agency or its local delegate agency. *See* 42 C.F.R. § 430.0. Payments are made based on types and ranges of services, payment levels for services, and administrative and operating procedures established by the State in accordance with Federal laws, statutes and rules. *Id.*

C. Other Federal Payer Programs.

44. The federal government also provides reimbursement for medical care under other healthcare programs.

45. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (presently entitled "TRICARE"), 10 U.S.C. §§ 1071-1106, is a federally-funded program administered by the Department of Defense. TRICARE/CHAMPUS provides medical benefits to certain active duty service members and their spouses and unmarried children, certain retired service members and their spouses and unmarried children, and reservists called to duty and their spouses and unmarried children. 32

C.F.R. § 199 *et seq.* TRICARE pays for its beneficiaries' medical procedures alleged herein.

46. CHAMPVA is a healthcare program administered by the United States Department of Veterans Affairs for families of veterans with 100 percent service-connected disabilities. CHAMPVA pays for its beneficiaries' medical procedures alleged herein.

47. The Federal Employees Health Benefits Program ("FEHBP") provides health care coverage for qualified federal employees and their dependants. FEHBP pays for its beneficiaries' medical procedures alleged herein.

48. The coverage and reimbursement criteria of these other federal payer programs mirror those of Medicare and Medicaid. The services provided beneficiaries must be reasonable and medically necessary. Health care providers are not permitted to seek reimbursement for services or procedures that are not reasonable or medically necessary.

V. THE LAW.

A. The FCA.

49. The Federal FCA, 31 U.S.C. §§ 3729-3733, provides, *inter alia*, that any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim made, is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

50. The Federal FCA also provides that any person who conspires to violate any provision of the Federal FCA is liable to the United States for a civil money penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(C).

51. The terms "knowing" and "knowingly" are defined to mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). These terms "require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B).

52. The term "claim" is defined to mean "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

53. The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. 31 U.S.C. § 3729(b)(4).

B. Anti-Kickback Statute.

54. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b(b) ("Anti-Kickback Statute"), provides criminal penalties of no more than $25,000 or five years in jail or both for the following:

> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. . . .
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program
>
> * * *
>
> (2) whoever knowingly and willfully offers and pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b).

55. A kickback in violation of the Anti-Kickback Statute violates the FCA.

56. A "federal health care program" is defined at 42 U.S.C. § 1320a-7b(f) as any plan or program providing health benefits funded, whether directly or indirectly, by

the United States Government. The statute applies to the performance of medical procedures. It requires that the professional judgment of the provider, and not financial considerations, guide the decision to perform medical procedures.

57. Federal regulations identify narrow "safe harbors" that do not violate the Anti-Kickback Statute. No safe harbor applies to the conduct alleged herein.

58. The Patient Protection and Affordability Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (H.R. 3590), which was signed into law on March 23, 2010, specifically makes a violation of the Anti-Kickback Statute actionable under the FCA. PPACA amended the Anti-Kickback Statute to provide that a "claim that includes items or services resulting from a violation [of the Anti-Kickback Statute] constitutes a false or fraudulent claim" under FCA. H.R. 3590, § 6402(f)(1). Moreover, it also clarified that actual knowledge of the Anti-Kickback Statute or specific intent to commit an Anti-Kickback Statute violation is not required for liability. H.R. 3590, § 6402(f)(2).

59. Compliance with the Anti-Kickback Statute is a precondition to participation in the Federal Payer Programs and to receive payment from the United States under Medicare pursuant to 42 C.F.R. § 413.24(f)(4)(iv). For example, providers certify on CMS 855A when enrolling in Medicare that they "agree to abide by Medicare laws, regulations and program instructions that apply to me. . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark Law), and on my compliance with all application conditions of participation in Medicare." Therefore, by seeking payment from the United States, healthcare providers certify their compliance with the

Anti-Kickback Statute, and the failure to comply renders the provider ineligible for payment.

60. The State of Kentucky has enacted anti-kickback statutes, the provisions of which mirror the Anti-Kickback Statute. Relators assert claims under these State anti-kickback laws.

C. The Stark Law.

61. The Ethics in Patient Referrals Act of 1989 § 6204, Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (Dec. 19, 1989) (codified at 42 U.S.C. § 1395nn) ("Stark I") as amended by the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13,562, 107 Stat. 312 (Aug. 10, 1993) ("Stark II"), the Patient Protection and Affordability Care Act, Pub. L. No. 111-148, §§ 6001(a), 6003(a), 124 Stat. 119 (Mar. 23, 2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106, 124 Stat. 1029 (Mar. 30, 2010) (collectively, "Stark Law") sets forth extensive prohibitions on the referrals that a physician can make when such referrals are tied to financial gain:

> (1) In general—Except as provided in subsection (b) of this section, if a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—
>
> > (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
> >
> > (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
>
> (2) Financial relationship specified—For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician with an entity specified in this paragraph is—

> (A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or
>
> (B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.
>
> An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in an entity providing the designated health service.

42 U.S.C. § 1395nn(a)(1)-(2).

62. The phrase "designated health services" is defined to include clinical laboratory services; physical therapy services occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services; and outpatient speech-language pathology services.

63. A referral in violation of the Stark Law violates the FCA.

64. Federal regulations identify narrow "safe harbors" that do not violate the Stark Law. No safe harbor applies to the conduct alleged herein.

65. Compliance with the Stark Law is a precondition to participation in the Federal Payer Programs and to receive payment from the United States under Medicare pursuant to 42 C.F.R. § 413.24(f)(4)(iv). For example, providers certify on CMS 855A when enrolling in Medicare that they "agree to abide by Medicare laws, regulations and

program instructions that apply to me. . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark Law), and on my compliance with all application conditions of participation in Medicare." Therefore, by seeking payment from the United States, healthcare providers certify their compliance with the Stark Law, and the failure to comply renders the provider ineligible for payment.

66. The false certification of compliance with the Stark Law results in liability under the FCA.

67. The federal-state Medicaid program in each state requires providers to comply with all Medicaid requirements in Federal laws. This includes, as a condition of payment, compliance with the Stark Law. The State of Kentucky has enacted anti-referral laws, the provisions of which mirror the Stark Law. Relators assert claims under the Kentucky State self-referral laws.

V. DEFENDANTS' WRONGFUL CONDUCT.

68. Relators Michael R. Jones, M.D., Paula W. Hollingsworth, M.D., and Michael G. Rukavina, M.D. are interventional cardiologists with a long-standing and well-respected cardiology practice, Lexington Cardiology at Central Baptist Hospital f/k/a/ Lexington Cardiology Consultants, in Lexington, Kentucky. Relators provide a complete range of cardiovascular services to patients, including diagnostic testing, interventional cardiology, and electrophysiology services. Relators have staff privileges at Saint Joseph Hospital in Lexington, are Fellows of the American College of Cardiology, and are board certified in their areas of expertise.

69. By virtue of their cardiology practice and participation in the Saint Joseph Hospital community, Relators were ideally situated to investigate and uncover the fraudulent conduct alleged in this Complaint. As staff cardiologists at Saint Joseph Hospital in Lexington, Kentucky, they routinely interact with cardiologists and staff members in the Saint Joseph Hospital community and have personal knowledge of the way in which the hospital operates. Due to their proximity to London, Kentucky and participation in the medical community, Relators have had past interactions with Defendants. They also consult with physicians in other disciplines with staff privileges at St. Joseph London Hospital or with private practices in the community.

70. Relators are often contacted by other physicians to treat patients suffering from on-going symptoms and complications due to previous diagnostic and therapeutic cardiac and vascular procedures performed by Defendants. This has conferred upon Relators direct and independent knowledge of Defendants' fraudulent conduct and has enabled them to discover and investigate the routine and illegal practices of Defendants, as alleged herein.

A. Medically Unnecessary Procedures.

71. Defendants have engaged in an unlawful scheme to maximize the reimbursements paid by the Federal Payer Programs for diagnostic and therapeutic cardiac and vascular procedures. Defendants Medical Specialists of Kentucky (owned by Defendant Chatterjee), Heart Clinic of Southeast Kentucky (owned by Defendant Anand), and Cumberland Clinic (jointly owned by Defendants Chatterjee and Anand) (collectively, "Defendant Clinics") have a monopoly over the cardiology and vascular practice in central and eastern Kentucky and control the referral of patients to hospitals

for cardiac and vascular procedures in this area. This has enabled them to gain dominant negotiating leverage with Defendant St. Joseph Health System, whose total revenue depends heavily on number of cardiac procedures performed at its hospitals, especially St. Joseph London Hospital.

72. Defendants Chatterjee and Anand use their market power to control the cardiac and vascular practices at St. Joseph London Hospital, including, but not limited to, billing, quality control and utilization review, performance of cardiac and vascular procedures, catheterization laboratory access, and the approval of cardiologists who receive staff privileges at St. Joseph London Hospital. Upon information and belief, every cardiologist with staff privileges at St. Joseph London Hospital is employed by Defendant Clinics. Defendant Clinics perform their diagnostic testing and imaging at their offices located at 1210 West 5th Street and 1380 Highway 192 East in London, Kentucky and, as discussed below, they have an illegal arrangement to refer patients exclusively to St. Joseph London Hospital and the other hospitals operated by Defendant St. Joseph Health System for therapeutic cardiac and vascular procedures.

73. Defendants Chatterjee and Anand, through Defendant Clinics, act in concert with Defendant St. Joseph Health System, to knowingly submit false and fraudulent claims for payment to the Federal payer programs for medically unnecessary coronary and vascular diagnostic and therapeutic procedures and falsely document in patient records the appropriateness of such procedures. To facilitate and conceal the scheme, Defendant St. Joseph Health System has knowingly failed to implement mandatory protocols, including a data driven quality assurance and peer review program, to detect the performance of unnecessary procedures and promote patient safety. Instead,

Defendant St. Joseph Health System put into practice sham review procedures controlled by Defendants Chatterjee and Anand and other co-conspirators. Defendant St. Joseph Health System's intentional failure to effectively review high-risk procedures for medical necessity have allowed Defendants Chatterjee and Anand to go undetected for years.

74. This Complaint challenges three types of procedures performed by Defendants: (i) diagnostic and therapeutic cardiac procedures, including diagnostic cardiac tests, diagnostic cardiac catheterizations, cardiac angioplasties, coronary stents, and CABGs, to diagnose and treat patients with coronary artery disease ("CAD"); (ii) diagnostic and surgical procedures used to implant temporary and permanent pacemaker devices in patients with heart arrhythmias; and (iii) therapeutic vascular procedures, including percutaneous transluminal arterial angioplasty ("PTA") and stenting in the vascular beds of patients, including the renal, iliac, and superficial femoral arteries.

75. First, Defendants have knowingly and routinely performed therapeutic cardiac catheterizations and stenting when it is not reasonable or necessary for the treatment of the patient. The CAD patients targeted by Defendants under this part of the scheme suffer from the build-up of plaque on their blood vessels, which causes the vessels to narrow (known as stenosis) and restricts the flow of blood, oxygen, and nutrients to the heart. To determine which procedures would be reasonable and necessary for the treatment of each patient, cardiologists perform diagnostic tests, including, for example, stress tests, echocardiograms, or electrocardiograms. In some cases, diagnostic cardiac catheterizations are performed by inserting a long, thin catheter through the blood vessels and into the coronary arteries using an x-ray machine. A coronary angiogram is created by injecting a contrast material through the catheter as x-rays are taken.

76. Intravascular ultrasound ("IVUS"), an imaging procedure used to obtain detailed images of the patient's blood vessels, and fractional flow reserve ("FFR"), a procedure to measure blood pressure and flow through a patient's coronary artery, are two additional diagnostic procedures that can be performed along with a cardiac catheterization. Although these procedures are available to defendants, they generally are not utilized and/or not properly documented in patients' medical records.

77. If one or more of the coronary arteries is blocked, one treatment option is a procedure known as a percutaneous transluminal coronary angioplasty ("PTCA"), which reopens the blocked artery by inserting a balloon catheter through the arteries and into the patient's heart and inflating a small balloon at the end of the catheter inside the blocked artery. The balloon expands the blocked vessel, allowing blood to flow more freely.

78. Physicians may also implant a bare metal or drug-eluting stent, which is a small metal tube implanted in the vessel to keep the artery permanently open. The well-recognized standard of care for the implantation of coronary stents in patients is that the blockage (stenosis) of the target artery must be greater than or equal to 70 percent as determined by ultrasound and other recognized diagnostic tests.

79. Defendants' fraudulent scheme to perform therapeutic cardiac procedures, including PTCAs and stents, that are not reasonable or necessary to treat the patients' CAD is effectuated by Defendant Clinics, which perform the diagnostic tests. Even though such tests indicate that a PTCA or PTCA with stent is not reasonable or appropriate for the treatment of the patient, Defendant Clinics, directly and through their agents, employees, and owners, including Defendant Cardiologists, falsely document the

existence or extent of a lesion in the patients' medical records and refer them to Defendant St. Joseph Health System, where the unnecessary procedures are then performed by the cardiologists employed by Defendant Clinics. In many instances, Defendants order patients to have routine follow up visits to undergo further unnecessary diagnostic testing. The unnecessary procedures were performed with the knowledge and authorization of Defendant St. Joseph Health System, which profits from the scheme.

80. To illustrate the unnecessary procedures, the following patient-specific examples demonstrate that Defendants knowingly performed diagnostic and therapeutic cardiac catheterizations, including PTCA and PTCA with stenting, that were not reasonable or necessary for the diagnosis or treatment of their patients:

a. **PATIENT A.** On December 16, 2009, Patient A presented to Relators with persistent chest pain at rest or exertion with palpitations and persistent pain following six cardiac catheterizations with seven coronary stents performed by Defendant Patil at St. Joseph London Hospital. Based on Relators' treatment of Patient A and their review of the medical records and imaging, Patient A had non-obstructive coronary artery disease and, therefore, the invasive cardiac procedures were not reasonable or necessary for the treatment of the patient. Defendant Patil performed the following medically unnecessary cardiac procedures on Patient A at St. Joseph London Hospital: (i) a left heart catheterization with two stents implanted in the diagonal and right coronary arteries on April 3, 2009; (ii) a left heart catheterization with a stent in the left anterior descending coronary artery on April 13, 2009; (iii) a left heart catheterization with a stent implanted in the myocardial bridge on June 17, 2009; (iv) a PTCA with a stent in the left anterior descending coronary artery due to restenosis on October 2, 2009; (v) a PTCA

with a stent of the diagonal coronary artery on October 15, 2009; and (vi) kissing stents placed in the diagonal left anterior descending artery with no lesion on November 11, 2009.

b. **PATIENT B.** On December 21, 2009, Patient B presented to Relators with increased chest pain following a cardiac catheterization with two stents performed by Defendant Patil at St. Joseph London Hospital. Specifically, Defendant Patil performed a cardiac catheterization with a stent implanted in the left main coronary artery that was not obstructed and another stent implanted in the right coronary artery was near normal. Based on Relators' treatment of Patient B and their review of the medical records and imaging, the patient's left main coronary artery was not obstructed, and the right coronary artery was normal. The procedures performed by Defendant Patil were not reasonable or necessary for the treatment of the patient.

c. **PATIENT C.** On August 2, 2010, Defendant Patil performed a medically unnecessary PTCA with stent in a bypass graft to the diagonal coronary artery. The procedure took place at St. Joseph London Hospital. Based on Relators' treatment of Patient C and their review of the medical records and imaging, the PTCA with stent was not reasonable or appropriate for the treatment of the patient because obstructive disease was absent.

d. **PATIENT D.** On February 12, 2010, Raul Vilca, M.D., a cardiologist employed by Defendant Clinics with staff privileges at St. Joseph London Hospital, performed a medically unnecessary PTCA with drug-eluting stent in the left anterior descending coronary artery of the patient. Based on Relators' treatment of Patient D and their review of the medical records, Patient D's stenosis in the left anterior

descending coronary artery was only 30 percent, and the CAD was non-obstructive in nature. The PTCA with stent was not reasonable or appropriate for the treatment of this patient. Moreover, the procedure later resulted in an adjacent diagonal artery with 70 percent narrowing of a previously normal blood vessel.

e. **PATIENT E.** On August 4, 2009, Defendant Patil performed a PTCA with stent in the left anterior descending coronary artery and a PTCA with stent in the distal right coronary artery in a patient with non-obstructive CAD. The procedures took place at St. Joseph London Hospital. Based on Relators' treatment of Patient E and their review of the medical records and imaging, the patient's stenosis was non-obstructive in nature and, therefore, the PTCA with stent was not reasonable or appropriate for the treatment of the patient.

f. **PATIENT F.** On February 8 and 9, 2010, Srikanth Sadhu, M.D., a cardiologist employed by Defendant Clinics with staff privileges at St. Joseph London Hospital, performed two PTCAs with stents placed in the left anterior descending and the circumflex coronary arteries of a patient with non-obstructive CAD. The procedures took place at St. Joseph London Hospital. Based on Relators' treatment of Patient F and their review of the medical records and imaging, the PTCAs with stents were not reasonable or necessary for the treatment for the patient.

g. **PATIENT G.** On February 20, 2008, Defendant Patil performed a medically unnecessary cardiac catheterization and implanted a stent in the mid-left anterior descending coronary artery of Patient G at St. Joseph London Hospital. Based on Relators' treatment of Patient G and their review of the medical records and imaging,

the cardiac catheterization and stent were not a reasonable or necessary method of treatment for the patient.

h. **PATIENT H.** On June 9, 2008, Suresh Rekhraj, M.D. performed a medically unnecessary cardiac catheterization with stent in the patient's right coronary artery at St. Joseph London Hospital. Based on Relators' treatment of Patient H and their review of the medical records and imaging, Patient H's CAD was non-obstructive in nature. Therefore, the cardiac catheterization and stent were not a reasonable or necessary method of treatment for the patient.

i. **PATIENT K.** From January 27, 2007 to January 3, 2011, Patient K underwent 17 medically unnecessary coronary catheterizations, including 7 PTCAs and 8 stents, at St. Joseph London Hospital. The medically unnecessary procedures were performed by Defendant Patil (diagnostic coronary catheterizations on January 27, 2007, March 7, 2008, July 7, 2008, October 15, 2008, May 4, 2009, and September 28, 2009; PTCAs with stents July 9, 2008, September 10, 2008, September 11, 2008, October 16, 2008, December 31, 2008, and February 12, 2009; and a PTCA August 18, 2008) and Defendant Chatterjee (diagnostic coronary catheterization on August 15, 2007). Defendants falsely documented the extent or existence of CAD in Patient K's medical records. Based on Relators' treatment of Patient K and their review of the medical records and imaging, the procedures performed by Defendants Patil and Chatterjee were not reasonable or necessary for the treatment of the patient.

j. **PATIENT L.** Patient L has undergone annual cardiac catheterizations performed by Anis Chalhoub, M.D., a physician employed by Defendant Clinics, at St. Joseph London Hospital for approximately 10 years. For example, on

January 28, 2008, Dr. Chalhoub performed a medically unnecessary cardiac catheterization after previous diagnostic testing revealed no significant CAD. Based on Relators' treatment of Patient L and their review of the medical records and imaging, the procedures performed by Dr. Chalhoub were not reasonable or necessary for the treatment of the patient.

k. **PATIENT O.** On August 24, 2009, Patient O had a PTCA with a stent implanted in the right coronary artery at St. Joseph Hospital. Defendants falsely documented the extent or existence of CAD in Patient O's medical records to justify medical necessity for this procedure. Based on Relators' treatment of Patient O and their review of the medical records and imaging, Patient O's right coronary artery contains only minor plaque. Therefore, the procedures performed at St. Joseph London Hospital were not reasonable or necessary for the treatment of the patient.

l. **PATIENT P.** On September 3, 2008, Defendant Patil performed a PTCA with stent placed in the left main coronary artery of Patient P with non-obstructive CAD. The procedure took place at St. Joseph London Hospital. Defendant Patil falsely documented the extent or existence of CAD in Patient P's medical records to justify medical necessity for the procedure. Based on Relators' treatment of Patient P and their review of the medical records and imaging, the PTCA with stent was not reasonable or necessary for the treatment for the patient.

m. **PATIENT Q.** Between November 10, 2008 and October 20, 2010, Patient Q underwent 10 cardiac catheterizations with 7 coronary stents at St. Joseph London Hospital, including repeated stenting in near normal arteries or arteries with insignificant lesions and repeated cardiac catheterizations without intervention.

Based on Relators' treatment of Patient Q and their review of the medical records and imaging, Patient Q had non-obstructive coronary artery disease. Therefore, the invasive cardiac procedures were not reasonable or necessary for the treatment of the patient. The medically unnecessary cardiac procedures performed on Patient Q at St. Joseph London Hospital include: (i) a diagnostic catheterization showing borderline disease in a very small distal non-dominant circumflex on November 10, 2008; (ii) stents placed in the left anterior descending artery and circumflex, both with less than 50 percent stenosis on February 10, 2009; (iii) stents placed in a near normal left anterior descending artery and diagonal on April 8, 2009; (iv) a stent placed in a circumflex with 20 percent stenosis on June 10, 2009; (v) an oversized stent place in a very distal marginal branch without significant runoff on October 29, 2009; (vi) angiography without procedure on January 27, 2010; (vii) a stent placed in the normal circumflex on February 10, 2010; (viii) angiography without intervention on June 11, 2010; and (ix) PTCA without intervention on October 20, 2010.

n. **PATIENT S.** Patient S underwent a PTCA with stent placement in the left anterior descending artery with less than 50 percent stenosis on July 29, 2010, a PTCA with stent placed in the right coronary artery with 10 percent stenosis on August 19, 2009, a PTCA with stent placed in the left anterior descending artery with borderline narrowing, and a PTCA in a near-normal artery on February 14, 2010, all of which were performed at St. Joseph London Hospital. Defendants falsely documented the extent or existence of CAD in Patient S's medical records to justify medical necessity for these procedures. Based on Relators' treatment of Patient S and their review of the medical

records and imaging, these invasive cardiac procedures were not reasonable or necessary for the treatment of the patient.

o. **PATIENT T.** On August 28, 2008, Patient T underwent a PTCA with stents placed in borderline lesions in two sapphenous vein grafts to the right coronary artery and circumflex. On September 24, 2010, Patient T was re-treated with a PTCA with stents in the same borderline lesions. Defendants falsely documented the extent or existence of CAD in Patient T's medical records. These procedures were performed at St. Joseph London Hospital. Based on Relators' treatment of Patient T and their review of the medical records and imaging, these invasive cardiac procedures were not reasonable or necessary for the treatment of the patient.

p. **PATIENT U.** Defendant Patil performed PTCAs with stents placed in Patient U's left anterior descending artery with 30 percent stenosis on June 27, 2008 and again on April 6, 2009. On April 23, 2010, Defendant Patil performed a PTCA with stent placed in a non-obstructed diagonal artery. These procedures were performed at St. Joseph London Hospital. Defendant Patil falsely documented the extent or existence of CAD in Patient U's medical records to justify medical necessity. Based on Relators' treatment of Patient U and their review of the medical records and imaging, these invasive cardiac procedures were not reasonable or necessary for the treatment of the patient.

q. **PATIENT V.** On April 14, 2009 a cardiac catheterization performed by Oluwole John Abe, M.D. revealed normal left ventricle function and minor non-obstructive CAD. Nonetheless, on April 15, 2009, Minoo Kavarana, M.D. performed an unnecessary double CABG of the left anterior descending and circumflex

arteries. On November 23, 2009, Defendant Patil performed a PTCA with stent placement in the non-obstructed left anterior descending artery. This stent was placed over a bypass graft that had been placed to the non-obstructed LAD. On March 5, 2010, Defendant Patil performed another PTCA with stent placed in the right coronary artery with 20 percent stenosis. These procedures were performed at St. Joseph London Hospital. Based on Relators' treatment of Patient V and their review of the medical records and imaging, Patient V had non-obstructive CAD. Therefore, these invasive cardiac procedures were not reasonable or necessary for the treatment of the patient.

r. **PATIENT W.** On March 5, 2009, Olawale Olatunji, M.D. performed a cardiac catheterization on Patient W and identified 60-70 percent stenosis in the circumflex artery and no more than minor plaque (20 percent) in the distal right coronary artery. Defendant Patil placed stents in both lesions, despite a clear lack of indication for intervention in the distal RCA. On August 31, 2009, Srikanth Sadhu, M.D. examined Ms. Gilliam and found no vessel with more than 50 percent stenosis. Nonetheless, Dr. Sadhu performed a PTCA and re-stented the proximal left circumflex coronary artery. He also place two additional stents in the right coronary artery with no more than 20 percent stenosis, but falsely documented in Patient W's medical records the presence of 80 percent stenosis. These procedures were performed at St. Joseph London Hospital. Based on Relators' treatment of Patient W and their review of the medical records and imaging, these invasive cardiac procedures were not reasonable or necessary for the treatment of the patient.

s. **PATIENT CC.** On October 25, 2010, Suresh Rekhraj, M.D. performed a PTCA with stent placed in Patient CC's mid-left anterior descending artery.

The procedure was performed at St. Joseph Hospital in Lexington, Kentucky. Dr. Rekhraj falsely documented Patient CC's medical condition to justify medical necessity for the procedure. Based on Relators' treatment of Patient CC and their review of the medical records and imaging, Dr. Rekhraj placed the stent in a near-normal vessel (less than 10 percent narrowing). Therefore, this invasive cardiac procedure was not reasonable or necessary for the treatment of the patient.

81. Second, Defendant Clinics, directly and through their agents, employees, and co-conspirators, including Defendant St. Joseph Health System, have knowingly and routinely performed surgical procedures known as coronary artery bypass grafts ("CABG") in patients. CABG is an alternative treatment to PTCA for patients with CAD. If one or more of the coronary arteries is blocked, a healthy artery or vein from the body may be connected, or grafted, to the blocked coronary artery. The grafted artery or vein bypasses the blocked portion of the coronary artery to create a new pathway for blood to flow freely to the heart.

82. Defendants' fraudulent scheme to perform medically unnecessary CABG in patients is effectuated by Defendant Clinics, which perform the diagnostic tests. Even though such tests indicate that a CABG is not reasonable or appropriate for the treatment of the patient, Defendant Clinics, directly and through their agents, employees, and owners, including Defendant Cardiologists, falsely document the existence or extent of a lesion in the patients' medical records and refer them to Defendant St. Joseph Health System, where the unnecessary procedures are then performed by the cardiologists employed by Defendant Clinics. The unnecessary procedures were performed with the

knowledge and authorization of Defendant St. Joseph Health System, which profits from the scheme.

83. To illustrate the unnecessary procedures, the following patient-specific examples demonstrate that Defendants knowingly performed CABGs that were not reasonable or necessary for the treatment of their patients:

a. **PATIENT K.** On February 1, 2007, Dermot Halpin, M.D., performed a CABG at St. Joseph Hospital in Lexington, Kentucky on Patient K. Defendants falsely documented the extent of Patient K's CAD (80 percent stenosis of the mid-left anterior descending artery and 80-90 percent stenosis of the ostial circumflex) to justify medical necessary for the procedure. On May 9, 2009, Dr. Halpin performed another CABG on Patient K at St. Joseph Hospital in Lexington, Kentucky. Based on Relators' treatment of Patient K and their review of the medical records and imaging, these procedures were not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

b. **PATIENT O.** On August 24, 2009, Minoo Kavarana, M.D. performed a double vessel CABG on Patient O at St. Joseph London Hospital. Based on Relators' treatment of Patient O and their review of the medical records and imaging, the patient had non-obstructive CAD. Therefore, the CABGs were not reasonable or necessary for the treatment of the patient. Following the surgery, Patient O's veins closed due to competitive flow through the non-obstructive vessels.

c. **PATIENT Q.** On November 10, 2008, Patient Q underwent a cardiac catheterization at St. Joseph London Hospital that showed borderline disease in a very small distal non-dominant circumflex. On December 10, 2008, Patient Q underwent

a triple vessel CABG. Based on Relators' treatment of Patient Q and their review of the medical records and imaging, the patient had non-obstructive CAD. The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

d. **PATIENT T.** On September 5, 2007, Patient T underwent a cardiac catheterization at St. Joseph London Hospital and was found to have non-obstructive CAD. Nonetheless, on or about September 7, 2007, Minoo Kavarana, M.D. performed a triple-vessel CABG on Patient T at St. Joseph London Hospital. Based on Relators' treatment of Patient T and their review of the medical records and imaging, the patient had non-obstructive CAD. The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

e. **PATIENT U.** On May 21, 2009, Defendant Patil performed a cardiac catheterization on Patient U at St. Joseph London Hospital that revealed no stenosis of angiographic significance in the coronary tree. On May 26, 2009, James Shoptaw, M.D. and Minoo Kavarana, M.D. performed a CABG at St. Joseph London Hospital for "severe coronary artery disease involving the stent in the left anterior descending coronary artery and severe stenosis in the ramus intermedians coronary artery." Based on Relators' treatment of Patient U and their review of the medical records and imaging, the patient had non-obstructive CAD. The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

f. **PATIENT V.** On April 13, 2009, Patient V underwent a cardiac catheterization performed by Oluwole John Abe, M.D. at St. Joseph London Hospital that showed non-obstructive CAD. On April 15, 2009, Minoo Kavarana, M.D. performed a double vessel CABG on Patient V at St. Joseph London Hospital. Based on Relators' treatment of Patient V and their review of the medical records and imaging, the patient had non-obstructive CAD. The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

g. **PATIENT X.** On July 21, 2010, Anis Chalhoub, M.D. performed a cardiac catheterization on Patient X at St. Joseph London Hospital that revealed a normal ventricular function and a single borderline stenosis (60 percent) in a branch of the left anterior descending artery. Nonetheless, James Shoptaw, M.D. performed a quadruple vessel CABG on Patient X at St. Joseph London Hospital. In his discharge report, Dr. Shoptaw falsely stated that Patient X's coronary arteries were narrowed by 60 percent, 80 percent, and 90 percent, respectively. Based on Relators' treatment of Patient X and their review of the medical records and imaging, the patient had non-obstructive CAD. The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

h. **PATIENT AA.** On February 15, 2006, Ashwini Anand, M.D. performed a cardiac catheterization on Patient AA and reported 70-75 percent narrowing of the distal left main coronary artery and 80-90 percent narrowing at the ostium of the left anterior descending artery. On February 16, 2006, Minoo Kavarana, M.D. and James Shoptaw, M.D. performed a double vessel CABG on Patient AA at St. Joseph London

Hospital. Based on Relators' review of the medical records and imaging, the distal left main coronary artery narrowing was no more than about 30 percent (not 70-75 percent as reported by Dr. Anand) and the reported narrowing of the ostium of the left anterior descending artery did not exist (not 80-90 percent as reported by Dr. Anand). The CABG was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality. In fact, based on Relators' treatment of Patient AA, the patient never experienced chest pain or discomfort until after the CABG performed by Drs. Shoptaw and Kavarana.

84. Third, Defendant Clinics, directly and through their agents, employees, and co-conspirators, including Defendant St. Joseph Health System, have knowingly and routinely performed surgical procedures to implant temporary and permanent pacemakers in patients. Pacemakers are indicated for patients with heart arrhythmias. Anis Chalhoub, M.D. and Oluwole John Abe, M.D., both of whom are employed by Defendant Clinics and have staff privileges at St. Joseph London Hospital, and other cardiologists employed by Defendant Clinics effectuate the scheme by performing diagnostic tests and imaging at their offices. Even though such tests indicate that the placement of a pacemaker is not reasonable or necessary for the treatment of the patient, they falsely document the patient's medical condition and refer the patient to Defendant St. Joseph Health System to have a pacemaker surgically implanted by Dr. Chalhoub, Dr. Abe, or other cardiologists employed by Defendant Clinics. These unnecessary procedures are performed with the knowledge and authorization of Defendant St. Joseph Health System, which profits from the scheme.

85. The following patient-specific examples demonstrate that Defendants knowingly implanted temporary or permanent pacemaker devices in patients without medical necessity:

a. **PATIENT C.** In or around August 2009, Anis Chalhoub, M.D., an employee of Defendant Medical Specialists of Kentucky, implanted a permanent pacemaker in Patient C at St. Joseph London Hospital. Dr. Chalhoub falsely documented Patient C's medical condition to justify medical necessity. Based on Relators' treatment of Patient C and their review of the medical records and imaging, the patient had no symptomatic or documented arrhythmias to clinically justify the placement of a pacemaker. It was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

b. **PATIENT I.** On November 17, 2010, Anis Chalhoub, M.D., implanted a permanent pacemaker device with subsequent left pneumothorax. The procedure took place at St. Joseph London Hospital five days after Dr. Chalhoub performed a coronary stent procedure in the same patient. Based on Relators' treatment of Patient I and their review of the medical records, the implantation of the pacemaker device was not reasonable or necessary for the treatment of the patient. Moreover, it is contraindicated to surgically implant a permanent pacemaker in patients with transient asymptomatic bradyarrhythmias following carotid stenting.

c. **PATIENT L.** On April 15, 2010, Anis Chalhoub, M.D. implanted a pacemaker device in Patient L at St. Joseph London Hospital. Dr. Chalhoub falsely documented Patient L's medical condition to justify medical necessity. Based on Relators' treatment of Patient L and their review of the medical records and imaging, the

patient had no symptomatic or documented arrhythmias to clinically justify the placement of a pacemaker. It was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality.

d. **PATIENT M.** On January 9, 1997, Anis Chalhoub, M.D. implanted a dual chamber pacemaker device in Patient M for neurocardiogenic synocope. Dr. Chalhoub falsely documented Patient M's medical condition to justify medical necessity. Based on Relators' treatment of Patient M and their review of the medical records and imaging, the patient had no clinical indications to justify the placement of a pacemaker. It was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality. The pacemaker was allowed to deplete and was not replaced at the end-of-life parameters.

e. **PATIENT R.** On September 22, 2010, Anis Chalhoub, M.D. implanted a dual chamber Boston Scientific pacemaker in Patient R for sick sinus syndrome with symptomatic bradycardia. Dr. Chalhoub falsely documented Patient R's medical condition to justify medical necessity for the procedure. Based on Relators' treatment of Patient R and their review of the medical records and imaging, the patient had no symptomatic or documented arrhythmias to clinically justify the placement of a pacemaker. It was not reasonable or necessary for the treatment of the patient, and it subjected the patient to an unreasonably increased risk of morbidity and mortality. The pacemaker was not replaced when it reached its end life.

f. **PATIENT X.** Patient X had a pacemaker implanted at St. Joseph London Hospital. Based on Relators' treatment of Patient X and their review of the medical records, the implantation of the pacemaker device was not reasonable or

necessary for the treatment of the patient, who had merely some nocturnal bradyarrhythmias.

g. **PATIENT Y.** In February 2003, Anis Chalhoub, M.D. implanted a Biotronik pacemaker device in Patient Y, which was later removed on July 20, 2007. Based on Relators' treatment of Patient Y and their review of the medical records, the implantation of the pacemaker device was not reasonable or necessary for the treatment of the patient.

h. **PATIENT Z.** On March 28, 2007, Anis Chalhoub, M.D. implanted a Biotronik pacemaker device in Patient Z, which was later removed on August 3, 2007 due to a pacemaker pocket infection. Dr. Chalhoub falsely documented Patient Z's medical condition to justify medical necessity for the procedure. Based on Relators' treatment of Patient Z and their review of the medical records and imaging, the patient had no symptomatic or documented arrhythmias to clinically justify the placement of a pacemaker. It was not reasonable or necessary for the treatment of the patient. The device was not replaced after being removed.

i. **PATIENT BB.** In December 2001, Defendant Chatterjee implanted a dual chamber pacemaker device in Patient BB. Based on Relators' treatment of Patient BB and their review of the medical records, the implantation of the pacemaker was not reasonable or necessary for the treatment of the patient. Patient BB is scheduled to have the device explanted.

86. Diagnostic and cardiac catheterization procedures, including PTCA and stents and pacemaker implantations, are lucrative procedures for the hospital in which they are performed and the physicians performing them. For example, the 2011

Medicare National Average Physician payment for a PTCA of a single vessel with stent (CPT 92980) at an inpatient facility is reimbursed $873.00. The 2011 Medicare National Average DRG payment for the same procedure is $9,902.00 per patient. The physician payment is increased by $243.00 for each additional vessel (CPT 92981), and the DRG payment is increased to $10,996.00 for placement of a drug-eluted stent. Likewise, the 2010 physician reimbursement rates for pacemaker implantation procedures (CPT 33208, 33214, 33224-26, 33249, and 33240) range from $446.00 to $878.00, and in 2011, the inpatient DRG reimbursement ranged from $11,390 (permanent cardiac pacemaker implant w/o CC/MCC) to $20,816.00 (permanent cardiac pacemaker implant w/MCC) per patient.

87. Not only were these procedures medically unnecessary, but they were also contraindicated by recognized medical standards and deviated from the standard of care by subjecting the patients to unnecessary increased morbidity and mortality risks as a consequence of the procedures. As shown by the examples set forth in the patient exemplars provided above, these procedures did, in fact, result in the injury of patients.

88. Defendants have knowingly submitted, or caused to be submitted, false and fraudulent claims for reimbursement to the Federal Payer Programs for the procedures described above, even though regulations, national coverage restrictions, and local coverage determinations specify that only medical services that are reasonable and necessary for the diagnosis and treatment of the illness or injury are covered under the Federal Payer Programs. Based on Relators' examination of the medical records and documents for the specific patients and procedures identified herein and other patients treated by Defendants, as well as their general knowledge and understanding of the

billing and reimbursement procedures of Defendant St. Joseph Health System as staff cardiologists at Saint Joseph Hospital, Relators state that claims for payment for the unnecessary procedures were made on the Federal Payer Programs.

89. Defendant MSO is a billing company owned and operated by Defendant Chatterjee's wife, Sumita Chatterjee. Upon information and belief, Defendant Chatterjee continues to have an ownership and/or financial interest and exerts control over the operations of Defendant MSO. Defendant MSO is responsible for submitting claims for payment to the Federal Payer Programs for the cardiac and vascular services and procedures provided by Defendant Clinics, Defendant St. Joseph Health System, and Defendant Premier Heart and Vascular Center.

90. With the knowledge and authorization of Defendant St. Joseph Health System, Defendants Chatterjee and Anand and other employees of Defendant Clinics, forwarded the information needed to bill the Federal Payer Programs for the medically unnecessary procedures described above, which were performed at Defendant Clinics, Defendant St. Joseph Health System, or Defendant Premier Heart and Vascular Center to Defendant MSO and authorized and instructed it to submit such claims for reimbursement to the Federal Payer Programs. The claims for reimbursement made false statements by Defendants that the procedures were reasonable and necessary.

91. Defendant MSO prepared and mailed or electronically transmitted the claims on Form 1500 to the Federal Payer Programs for reimbursement of such procedures. At all times, Defendants knew that these claims for payment or approval were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

92. Fourth, Defendants have also knowingly and routinely perform medically unnecessary therapeutic vascular procedures, including percutaneous transluminal arterial angioplasty ("PTA") and stenting in the vascular beds of patients, including, for example, the renal, iliac, and superficial femoral arteries. By way of example, on January 6, 2010, Patient S underwent a PTA with stent placed in the right iliac artery with less than 50 percent occlusion for a iatrogenic non-obstructive dissection at St. Joseph London Hospital. Defendants falsely documented Patient S's medical condition to justify medical necessity for the procedure. Based upon Relators' treatment of Patient S and their review of the medical records, this procedure was not reasonable or necessary for the treatment of the patient.

93. Moreover, upon information and belief, the stents used in these vascular procedures require, but did not possess, FDA approval for safety and efficacy to be implanted in the vascular beds of patients. Upon information and belief, in many instances, Defendants used Class II biliary stents, which contain labeling disclosures that the safety and efficacy of the devices in the vascular system have not been established. The lack of FDA approval for the stents was not communicated to patients, who have received the unapproved devices as permanent vascular bed implants. Defendants failed to obtain informed consent from patients regarding the use of unapproved devices.

94. Upon information and belief, Defendant St. Joseph Health System has market share rebate agreements that confer upon them a financial incentive for using biliary stents in vascular procedures, even though biliary stents lack the required FDA approval demonstrating that they are safe and effective for use the vascular procedures. The financial incentive is a kickback in violation of Anti-Kickback Statute.

95. At the direction and with the knowledge of Defendant St. Joseph Health System, Defendant Clinics, and Defendant Cardiologists, and Defendant MSO subsequently billed the Federal Payer Programs for these procedures, even though the coding and billing requirements restrict coverage to reimbursements to FDA approved Class III vascular stents which have been demonstrated to be safe and effective, not experimental or investigational.

B. Illegal Payment of Kickbacks and Stark Law Violations.

96. Defendant St. Joseph Health System provided illegal kickbacks to Defendant Clinics to induce them to refer patients for interventional diagnostic and therapeutic cardiac and vascular procedures at Defendant St. Joseph Health System, instead of other nearby hospitals.

97. The payment of kickbacks is tied to Defendants' scheme to bill the Federal Payer Programs for medically unnecessary therapeutic cardiac and vascular procedures, as set forth above. The payment of kickbacks provided Defendants with an incentive to pursue medically unnecessary treatments that are costly and pose health and safety risks to patients.

98. Defendant St. Joseph Health System entered into provider services agreements with Defendant Clinics and/or Defendants Chatterjee and Anand that provide payments to induce the referral of patients exclusively to Defendant St. Joseph Health System for the cardiac and vascular procedure challenged herein. Under these agreements, Defendant Clinics and Defendants Chatterjee and Anand received payments that were above market value, for services not performed, and that were not

commercially reasonable and were entered into for the purpose of inducing referrals by them to Defendant St. Joseph Health System.

99. Upon information and belief, Defendant Chatterjee previously owned and operated an outpatient office that performed cardiac and vascular catheterizations entitled The Heart Doctors, P.S.C. (now known as Defendant Medical Specialists of Kentucky). Aware that Defendants Chatterjee and Anand, through Defendant Clinics, controlled the cardiology and vascular medical practice in London, Kentucky, Defendant St. Joseph Health System purchased the practice from Defendant Chatterjee. To induce the referral of patients, Defendant St. Joseph Health System, through the guise of provider services agreements, pays Defendant Clinics and/or Defendants Chatterjee and Anand a portion of the inpatient and outpatient facility reimbursement (DRG and/or APC) for each patient referred to the hospital for the diagnostic and therapeutic cardiac and vascular tests and procedures challenged herein.

100. At all times, Defendants, including Defendant MSO, knew that these claims for payment or approval were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false. Nonetheless, Defendants have knowingly submitted, or caused to be submitted, false and fraudulent claims for reimbursement to the Federal Payer Programs in violation of the Anti-Kickback Statute.

101. Moreover, Defendant Clinics and Defendants Chatterjee and Anand engaged in a self-referral scheme intended to increase revenues at the expense and welfare of patients. Specifically, Defendants Chatterjee and Anand refer patients to cardiologists employed by Defendant Clinics and Defendant St. Joseph Health System

without revealing to those patients that they have a financial relationship with the cardiologists and Defendant St. Joseph Health System based on the number of patients referred for treatment, in violation of the Stark Law.

C. Defendants' Fraudulent Billing Scheme Regarding Place of Service.

102. Medicare Part B pays for services that physicians provide to program beneficiaries. Physician services include medical and surgical procedures, office visits, and medical consultations and may be provided in facility settings, such as hospital outpatient departments (Code 22), or in non-facility locations, such as physician offices (Code 11) and independent clinics (Code 49).

103. The amount of the physician charge varies depending on whether the service was provided in facility or non-facility location. 42 C.F.R. § 414.22 (b)(5)(i)(A)-(B). Generally, the physician payment is higher if the service is performed at a non-facility location, e.g., an office, in order to account for the increased practice expenses that physicians incur at their offices or other non-facility locations.

104. Even though the physician payment is lower if the service is performed at a facility location, e.g., an outpatient hospital department, the physician can bill for the physician payment plus the facility can bill for the outpatient facility reimbursement payment (which is intended to go to the facility itself, not the physician). Therefore, the overall reimbursement would be maximized by submitting a claim stating that the service was performed at a facility location insofar as the total reimbursement, i.e., physician charge plus the outpatient facility reimbursement, is much higher than only the non-facility physician rate.

105. Defendants, directly and through their employees, agents, and co-conspirators, have knowingly submitted, or have caused to be submitted, claims for reimbursement to the Federal Payer Programs that falsely and fraudulently coding the place of service. Specifically, Defendant St. Joseph Health System authorized Defendant Clinics to bill the Federal Payer Programs for diagnostic cardiac testing and imaging and other outpatient procedures, such as stress tests (CPT 93016-93018) and echocardiography (CPT 93306-93308), under the provider codes registered to Defendant St. Joseph Health System and/or Defendant Premier Heart and Vascular Center. This enables Defendant Clinics to bill the Federal Payer Programs for the lower non-facility physician payment, but also for the higher outpatient facility payment as well, which they were not entitled to receive.

106. To illustrate, on June 16, 2009, Defendant Anand treated Patient J at Defendant Medical Specialists of Kentucky located at 1210 West 5th Street in London, Kentucky. The procedures performed included intravenous therapy, nuclear diagnostic testing, EKG stress testing, and echocardiology services. The procedures were performed at Defendant Medical Specialists of Kentucky, but were billed as being performed at St. Joseph London Hospital. In this instance, Defendants Medical Specialists of Kentucky and Anand would submit a claim for the physician reimbursement, and St. Joseph London Hospital would submit a claim for the APC or DRG facility reimbursement. Additional patients include, by way of example, Patient B for diagnostic services performed on June 11, 2009.

107. The portion of the APC or DRG payment paid to Defendant Clinics and/or Defendants Chatterjee and Anand also constituted an illegal kickback intended to induce

the referral of patients to Defendant St. Joseph Health System in violation of the Anti-Kickback Statute and FCA.

108. As set forth above, Defendant Clinics, directly and through their agents, employees, and co-conspirators, including Defendants St. Joseph Health System and Premier Heart and Vascular Center, knowingly provided false statements as to the actual place of service to Defendant MSO with the instruction to prepare and submit claims for payment based on the false statements. At all times, Defendants, including Defendant MSO, knew that these claims for payment or approval were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false. Nonetheless, Defendants have knowingly submitted, or caused to be submitted, false and fraudulent claims for reimbursement to the Federal Payer Programs that falsely coded the actual place of service.

VI. DAMAGES.

109. The United States has been damaged by the acts and practices of Defendants, as described above, in presenting, causing to be presented, and conspiring to present false claims, statements and records to induce the payment for medically unnecessary diagnostic and therapeutic cardiac and vascular procedures and referrals based the payment of illegal kickbacks.

110. Defendants' false statements were material to the decision of the United States to cover and reimburse Defendants for the medically unnecessary procedures described herein.

111. Defendants profited unlawfully from the payment of the false and fraudulent claims.

112. Damages to the federal and state governments are substantial.

COUNT I

VIOLATIONS OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(A)

(Against All Defendants)

113. Relators restate and reallege the allegations contained in paragraphs 1-112 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

114. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), provides in relevant part that any person who:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

115. By virtue of the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment of diagnostic and therapeutic cardiac and vascular procedures that were not reasonable or necessary and do not accurately reflect the services furnished to patients. Defendants knew that these claims for payment or approval were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

116. Each claim presented or caused to be presented for reimbursement for the medically unnecessary procedures set forth herein represents a false or fraudulent claim for payment under the FCA.

117. Unaware that Defendants submitted false statements to conceal the routine performance of medically unnecessary diagnostic and therapeutic cardiac and vascular procedures and the place of service, and unaware that Defendants routinely violated the Anti-Kickback Statute and falsely certified compliance with the Stark Law and regulations despite pervasive and substantial non-compliance, the United States and the States paid and continue to pay the false claims submitted for Defendants' cardiac and vascular medical services. These claims would not have been paid but for Defendants' fraud and false statements.

118. In reliance on the accuracy of Defendants' data, representations, and certifications, the United States has paid said claims and has suffered financial losses because of these acts by Defendants.

COUNT II

VIOLATIONS OF THE FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)(B)

(Against All Defendants)

119. Relators restate and reallege the allegations contained in paragraphs 1-118 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

120. The False Claims Act, 31 U.S.C. § 3729(a)(1)(B), provides in relevant part that any person who:

> knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

121. By virtue of the acts described herein, Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment of diagnostic and therapeutic cardiac and vascular procedures that were not reasonable or necessary and do not accurately reflect the services furnished to patients. Defendants knew that the records or statements were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

122. Each claim presented or caused to be presented for reimbursement of one of Defendants' medically unnecessary diagnostic and therapeutic cardiac and vascular procedures or that falsely state the place of service represents a false or fraudulent record or statement under the Federal FCA.

123. Defendant St. Joseph Health System knowingly made or used false record or statements in hospital cost reports and quarterly credit balance reports by failing to disclose overpayments associated with the unnecessary procedures.

124. Unaware that Defendants submitted, or caused to be submitted, false records and/or statements to conceal the routine performance of medically unnecessary therapeutic cardiac and vascular procedures and practice of upcoding bills, and unaware that Defendants routinely violated the Anti-Kickback Statute and falsely certified compliance with the Stark Law, and regulations despite pervasive and substantial non-

compliance, the United States paid and continue to pay the false claims submitted for Defendants' medical services. These claims would not have been paid but for Defendants' fraud and false statements.

125. In reliance on the accuracy of Defendants' data, representations, and certifications, the United State has paid said claims and has suffered financial losses because of these acts by Defendants.

COUNT III

VIOLATIONS OF THE FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(C)

(Against All Defendants)

126. Relators restate and reallege the allegations contained in paragraphs 1-125 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

127. The False Claims Act, 31 U.S.C. § 3729(a)(1)(C), provides in relevant part that any person who:

> conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G) . . .
>
> > is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . plus three times the amount of damages which the Government sustains because of the act of that person. . . .

128. By virtue of the acts described herein, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and (B) by knowingly presenting, or causing to be presented, false or fraudulent claims for payment by knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims. Defendants knew that these claims were false, fraudulent, or fictitious, or were

deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

129. Unaware of the conspiracy to submit false records and/or statements to conceal the routine performance of medically unnecessary cardiac and vascular procedures and falsely state the place of service, and unaware that Defendants routinely violated the Anti-Kickback Statute and falsely certified compliance with the Stark Law and regulations despite pervasive and substantial non-compliance, the United States and the States paid and continue to pay the false claims submitted for Defendants' medical services. These claims would not have been paid but for Defendants' fraud and false statements.

130. In reliance on the accuracy of Defendants' data, representations, and certifications, the United States and the States have paid said claims and have suffered financial losses because of these acts by Defendants.

PRAYER AS TO COUNTS I-III

WHEREFORE, Relators pray that this District Court enter judgment on behalf of Relators and against Defendants in Counts I-III, respectively, for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States Government as a result of each Defendants' conduct;

b. Civil penalties against the Defendants, respectively, equal to not less than $5,000 and not more than $10,000, adjusted for inflation according to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, for each violation of 31 U.S.C. § 3729;

c. The fair and reasonable sum to which Relators are entitled under 31 U.S.C. § 3730(b); additionally, Relators are entitled, in equity, to recover attorneys' fees from the fund created for non-participating beneficiaries (those not contributing material time and expense to generating any settlement or recovery from any Defendant) under the Common Fund doctrine to be paid from the recovery fund generated for such non-participatory beneficiaries from the defendants;

d. All costs and expenses of this litigation, including statutory attorneys' fees and costs of court;

e. Pre-judgment and post-judgment, as appropriate, interest at the highest rate allowed by law;

f. Relators' individual damages, if any, which may be alleged; and

g. All other relief on behalf of Relators or the United States Government to which they may be justly entitled, under law or in equity, and the District Court deems just and proper.

COUNT IV

VIOLATIONS OF THE ANTI-KICKBACK STATUTE 42 U.S.C. § 1320a-7b

(Against All Defendants)

131. Relators restate and reallege the allegations contained in paragraphs 1-130 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

132. The Medicare and Medicaid Patient Protection Act of 1987, 42 U.S.C. § 1320a-7b, provides criminal penalties up to $25,000 or five years in jail or both for the following:

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program

* * *

(2) whoever knowingly and willfully offers and pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b).

133. Each claim for reimbursement for medically unnecessary cardiac and vascular procedures represents a false or fraudulent claim for payment because each procedure carried with it a false certification by Defendants that the service it provided complied with the Anti-Kickback Statute.

134. Defendant St. Joseph Health System has violated the Anti-Kickback Statute offering and knowingly and willfully providing and/or receiving a direct and substantial financial incentive in the form of kickbacks to induce Defendant Clinics to

refer patients to Defendant St. Joseph Health System for interventional diagnostic and therapeutic cardiac and vascular procedures and submitting false and fraudulent claims for reimbursement for such procedures. These kickbacks were received by and with the knowledge of hospitals and healthcare providers, including Defendant Clinics and Defendants Chatterjee, Anand, and Patil. No safe harbor provisions apply.

135. Defendant Clinics and Defendants Chatterjee, Anand, and Patil have violated the Anti-Kickback Statute by knowingly and willfully soliciting and/or receiving a direct and substantial financial incentive in the form of kickbacks to them to refer patients to Defendant St. Joseph Health System for interventional diagnostic and therapeutic cardiac and vascular procedures. No safe harbor provisions apply.

136. Unaware of the Defendants' violation of the Anti-Kickback Statute and the falsity of the records, statements, and claims made or caused to be made by Defendants, the United States paid and continues to pay on the claims that would not be paid but for Defendants' wrongful actions and omissions.

137. As violations of the Anti-Kickback Statute, the material misrepresentations made by Defendants to induce the unnecessary use of the devices constitute false claims and statements under 31 U.S.C. § 3729 *et seq.*

COUNT V

VIOLATIONS OF THE STARK LAW
42 U.S.C. § 1395nn

(Against All Defendants)

138. Relators restate and reallege the allegations contained in paragraphs 1-137 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

139. The Ethics in Patient Referrals Act of 1989 § 6204, Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (Dec. 19, 1989) (codified at 42 U.S.C. § 1395nn) ("Stark I") as amended by the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13,562, 107 Stat. 312 (Aug. 10, 1993) ("Stark II"), the Patient Protection and Affordability Care Act, Pub. L. No. 111-148, §§ 6001(a), 6003(a), 124 Stat. 119 (Mar. 23, 2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1106, 124 Stat. 1029 (Mar. 30, 2010) (collectively, "Stark Law") sets forth extensive civil prohibitions on the referrals that a physician can make when such referrals are tied to financial gain:

> (1) In general—Except as provided in subsection (b) of this section, if a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—
>
> > (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and
> >
> > (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).
>
> (2) Financial relationship specified—For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician with an entity specified in this paragraph is—
>
> > (A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or
> >
> > (B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.
>
> An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that

holds an ownership or investment interest in an entity providing the designated health service.

42 U.S.C. § 1395nn(a)(1)-(2).

140. Each claim for reimbursement for Defendants' medically unnecessary diagnostic or therapeutic cardiac and vascular procedures represents a false or fraudulent claim for payment because each such procedure carried with it a false certification by Defendants that the service it provided complied with the Stark Law.

141. Defendants St. Joseph London have violated the Stark Law by referring patients for treatment at Defendant Clinics with which they have a financial relationship as defined by the Stark Law and subsequently presented or caused to be presented claims for payment for designated health services, including diagnostic and therapeutic cardiac and vascular procedures, furnished as a result of the unlawful referral. Defendant Clinics and Defendants Chatterjee, Anand, and Patil have violated the Stark Law by referring patients for treatment to Defendants St. Joseph London and subsequently presented or caused to be presented claims for payment for designated health services, including diagnostic and therapeutic cardiac and vascular procedures, furnished as a result of the unlawful referral. These referrals were made by and with the knowledge of Defendants. No Safe Harbor provisions of the Stark Law apply.

142. Unaware of the falsity of the records, statements, and claims made or caused to be made by Defendants, and in reliance on the truthfulness and accuracy of their certifications, the United States paid and continues to pay on the claims that would not be paid but for Defendants' wrongful actions.

143. As violations of the Stark Law, the material misrepresentations made by Defendants to induce the unnecessary use of the devices constitute false claims and statements under 31 U.S.C. § 3729 *et seq.*

PRAYER AS TO COUNTS IV-V

WHEREFORE, Relators pray that this District Court enter judgment on behalf of Relators and against Defendants in Counts IV-V, respectively, as follows:

a. Damages suffered by the United States Government as a result of each Defendant's conduct;

b. Civil penalties against the Defendants, respectively, equal to $11,000 for each violation of 31 U.S.C. § 3729;

c. Relators be awarded the a fair and reasonable sum to which Relators are entitled under 31 U.S.C. § 3730(b); additionally, Relators are entitled, in equity, to recover attorneys' fees from the fund created for non-participating beneficiaries (those not contributing material time and expense to generating any settlement or recovery from any Defendant) under the Common Fund doctrine to be paid from the recovery fund generated for such non-participatory beneficiaries from the defendants;

d. Relators be awarded all costs and expenses of this litigation, including statutory attorneys' fees and costs of court;

e. Pre-judgment and post-judgment, as appropriate, interest at the highest rate allowed by law;

f. Relators' individual damages, if any, which may be alleged; and

g. All other relief on behalf of Relators or the United States Government to which they may be justly entitled, under law or in equity, which the District Court deems just and proper.

DEMAND FOR JURY TRIAL

Relators demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment to the U.S. Constitution.

Respectfully submitted,

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Counsel for Relators

August 8, 2012

CERTIFICATE OF SERVICE

I certify that on this 8th day of August, 2012, a true and correct copy of the foregoing First Amended Complaint was filed under seal with the Clerk of Court and was served on the following party listed below by U.S. Certified Mail, Return Receipt Requested:

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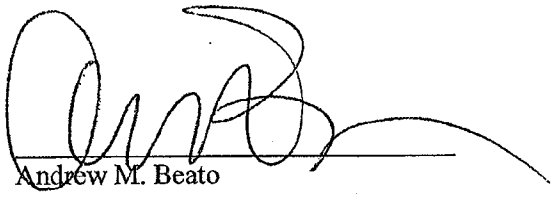

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